DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 20, 2015

Coloplast A/s
Brian Schmidt
Regulatory Affairs Manager
1601 West River Road North
Minneapolis, MN 55411

Re: K143182
Trade/Device Name: Speedicath Compact Male
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: GBM
Dated: January 7, 2015
Received: January 8, 2015

Dear Brian Schmidt,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K143182

Device Name: **SpeediCath** Compact Male

Indications for Use:

SpeediCath Compact Male is indicated for use by patients with urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. The catheter is for male patients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109

(Optional Format 1-2-96)

510(k) Summary

SpeediCath Compact Male

(as required per 21 CFR § 807.92)

The assigned 510(k) number is: _____

Submitter: Coloplast Corp
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Minneapolis, MN 55411

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Date Prepared: January 9, 2015

Device Name and Classification

Trade Name: **SpeediCath** Compact Male

Common Name: Urinary Catheter for Intermittent Use

Classification Name: Gastroenterology-Urology Devices

Product Code: GBM

Legal Manufacturer

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek Denmark

Device Description

The **SpeediCath** Compact Male is a sterile, single use, disposable polyurethane catheter for males. The catheter is pre-lubricated with a hydrophilic coating and immersed in saline solution. To prepare the catheter for use, the cover is removed and the catheter is pulled out of the packaging thereby extending and locking it to its full length. The catheter is then ready to use allowing easy drainage.

Substantial Equivalence Claim

The proposed **SpeediCath** Compact Male is substantially equivalent in form and function to Coloplast's **SpeediCath** Compact Set Male, which was cleared under 510(k) K121458 on October 1, 2012.

SpeediCath Compact Male and the predicate device are sterile, single use catheters for intermittent use with hydrophilic coatings.

Both **SpeediCath** Compact Male and the predicate device are ready to use catheters with identical hydrophilic coatings immersed in identical saline solution. Furthermore, both SpeediCath Compact Male and the predicate device uses the same type of catheter design: telescope catheter.

The main difference between **SpeediCath** Compact Male and the predicate device is the packaging configuration and visual appearance. **SpeediCath** Compact Male does not have a pre-attached urine collection bag like the predicate device. The **SpeediCath** Compact Male packaging configuration has the same ready to use features as the predicate, and is packaged in a green discrete container instead of a turquoise colored. Equivalent to the predicate device, **SpeediCath** Compact Male is short in storage and is extended to its full length due to the telescopic extension of the catheter.

Indications for Use

SpeediCath Compact Male is indicated for use by patients with urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain. This catheter is for male patients.

Summary of Testing

SpeediCath Compact Male has been tested and complies with relevant sections of ASTM F 623-99, ASTM D1894-11, EN 1616, EN 1617 and EN 1618.

Performance Testing included:

- Flow Rate
- Coefficient of Friction
- Tensile Strength

SpeediCath Compact Male has been tested and complies with relevant sections of ISO 10993, Biological Evaluation of Medical Devices.

Biocompatibility Testing included:

- Cytotoxicity
- Irritation
- Sensitization
- Colorant Leachable Study